

PCT

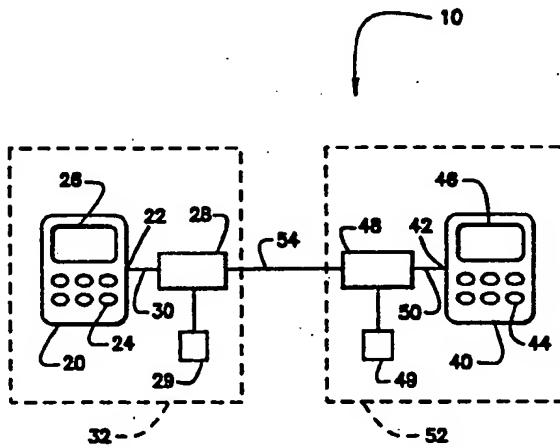
WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : <b>A61M 5/172, G06F 15/42</b>		A1	(11) International Publication Number: <b>WO 94/05355</b> (43) International Publication Date: <b>17 March 1994 (17.03.94)</b>
(21) International Application Number: <b>PCT/US93/08098</b>			(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: <b>26 August 1993 (26.08.93)</b>			
(30) Priority data: <b>07/942,288 9 September 1992 (09.09.92) US</b>			
(71) Applicant: <b>PHARMACIA DELTEC, INC. [US/US]; 1265 Grey Fox Road, St. Paul, MN 55112 (US).</b>			Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(72) Inventor: <b>BLOMQUIST, Michael, L. ; 2389 132nd Avenue N.W., Coon Rapids, MN 55448 (US).</b>			
(74) Agent: <b>BRUESS, Steven, C.; Merchant, Gould, Smith, Edell, Welter &amp; Schmidt, 90 South Seventh Street, 3100 Norwest Center, Minneapolis, MN 55402 (US).</b>			

(54) Title: **SYSTEMS AND METHODS FOR COMMUNICATING WITH AMBULATORY MEDICAL DEVICES SUCH AS DRUG DELIVERY DEVICES**



(57) Abstract

The present invention relates to systems and methods for communicating with ambulatory medical devices, such as drug delivery devices, both locally and remotely. In one embodiment, a caregiver drug pump communicates with a remote patient drug pump for data gathering, trouble shooting, and operational program changes. The caregiver drug pump is at least substantially identical in configuration to the patient drug pump. The caregiver drug pump transmits caregiver key input signals to the remote patient drug pump. The patient drug pump receives the key input signals, accesses a desired program, and transmits information for display on the display of the caregiver drug pump. In another embodiment, a computer is provided for communicating locally and/or remotely with a drug pump. The computer may include a display with an image of a pump. The computer may be operated through the use of a mouse or touch screen with respect to the image of the pump, to simulate use of the pump while using the personal computer. The computer may also be used as a training aid for training a caregiver and/or patient how to use the drug pump.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NE	Niger
BE	Belgium	GN	Guinea	NL	Netherlands
BF	Burkina Faso	GR	Greece	NO	Norway
BG	Bulgaria	HU	Hungary	NZ	New Zealand
BJ	Benin	IE	Ireland	PL	Poland
BR	Brazil	IT	Italy	PT	Portugal
BY	Belarus	JP	Japan	RO	Romania
CA	Canada	KP	Democratic People's Republic of Korea	RU	Russian Federation
CF	Central African Republic	KR	Republic of Korea	SD	Sudan
CG	Congo	KZ	Kazakhstan	SE	Sweden
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovak Republic
CM	Cameroon	LU	Luxembourg	SN	Senegal
CN	China	LV	Latvia	TD	Chad
CS	Czechoslovakia	MC	Monaco	TG	Togo
CZ	Czech Republic	MG	Madagascar	UA	Ukraine
DE	Germany	ML	Mali	US	United States of America
DK	Denmark	MN	Mongolia	UZ	Uzbekistan
ES	Spain			VN	Viet Nam
FJ	Finland				

SYSTEMS AND METHODS FOR COMMUNICATING WITH  
AMBULATORY MEDICAL DEVICES SUCH AS DRUG DELIVERY DEVICES

FIELD OF THE INVENTION

5 The present invention relates generally to ambulatory medical devices and methods for communicating with such devices. In particular, the present invention relates to systems and methods for locally and remotely communicating with drug delivery devices.

10

BACKGROUND OF THE INVENTION

Various ambulatory medical devices are known for treating and/or monitoring patients at a remote site away from the caregiver's or clinician's office. One 15 example of an ambulatory medical device is a drug delivery device, such as a drug pump, for providing periodic or continuous drug delivery to the patient when the patient is away from the caregiver's office.

Certain drugs rarely achieve their maximum 20 therapeutic action through conventional injection techniques. Many drugs reach their full potential only through precise delivery over an extended period of time. With controlled drug infusion through a drug pump, the drug can be given at a precise rate that will 25 keep the drug concentration within the therapeutic margin and out of the toxic range. Ambulatory drug pumps can provide appropriate drug delivery to the patient at a controllable rate which does not require frequent medical attention and which allows the patient 30 to leave the hospital or caregiver's office.

A failure to adequately monitor the drug pump and the patient's usage of the drug pump can reduce or eliminate any benefits the patient may have received from a proper drug delivery therapy. In some cases, the 5 drug therapies can have serious health consequences to the patient if the drugs are not administered properly.

Several concerns arise when the patient utilizes the various ambulatory medical devices at remote sites. If the ambulatory medical device gathers 10 data with respect to the device and/or the patient, the data needs to be easily accessible by the caregiver to permit the caregiver to monitor the device and the patient. Often, the patient may be of little or no assistance in accessing the data and communicating with 15 the caregiver from the remote site. If the caregiver needs to physically handle the device to access the data, the device and caregiver must be brought to the same, location.

Similar problems can also arise in that the 20 medical devices may fail or be used improperly at the remote sites. If the device is not operating properly, the device may have to be brought to the caregiver, or the caregiver may have to visit the patient. If the caregiver attempts to trouble shoot from a remote site, 25 the patient may be unable physically or mentally to sufficiently cooperate with the caregiver for the caregiver to trouble shoot from the remote site.

Operating problems can arise at inconvenient times, such as at night or on weekends and holidays. The caregiver may also need to be able to easily periodically monitor the patient's usage of the medical device to observe 5 patient compliance with prescribed treatments while the patient is at the remote site.

There may further arise a need for the caregiver to access the controller, such as the processor and the programs, which controls operation of 10 the ambulatory medical devices. For example, in the case of drug delivery devices, some therapies change over time. The caregiver may need to access the operating program in order to change the operation of the drug delivery device. Further, some drug delivery 15 devices, for example, may be used for very different applications, requiring different operating programs. These operating programs can be changed as the use of the drug delivery device changes. Resources may not be used efficiently if the caregiver and the device must be 20 brought to the same location for the caregiver to access the processor and operating programs.

One specific situation often arises in the case of a drug pump where the caregiver needs to access the controller of the drug pump. The caregiver may visit 25 the patient at the patient's home at some point after the drug therapy has begun using the drug pump. The caregiver may sample the patient's blood. The caregiver returns to the office and the blood sample is analyzed.

The results of the blood analysis may indicate the patient is not receiving the proper drug therapy. This usually means the controller of the drug pump must be adjusted to give the proper therapy to the specific 5 patient. To adjust the controller, the caregiver needs to be able access the controller.

Another problem facing caregivers in the area of ambulatory medical devices relates to the ease of remote communication with the devices, if such remote 10 communication capability is provided. Remote communication with an ambulatory medical device using a personal computer or base station may be difficult for some caregivers, if the personal computer/base station operates differently than the medical device. The 15 caregiver must then be knowledgeable both in operation of the medical device and in operation of the personal computer/base station. This concern also applies to local communication with the ambulatory medical device.

In the case of remote communication with a 20 patient's medical device using a personal computer/base station, the caregiver also needs to remain near the personal computer/base station, or else transport the personal computer/base station with the caregiver, if the caregiver wishes to remain in communication with the 25 patient's medical device.

It sometimes may become necessary to communicate with a personal computer or base station either locally or remotely in order to take advantage of the greater data handling or processing capability of the personal computer or base station, for example. The ability of the caregiver to communicate easily with the pump using a personal computer or base station may be important in those circumstances. In addition, the patient may be able to do very little to assist the caregiver in linking the remote medical device to the local personal computer/base station.

There is a need for systems and methods for communicating with ambulatory medical devices such as drug delivery devices, both locally and remotely, which addresses the above concerns and other concerns.

#### SUMMARY OF THE INVENTION

The present invention relates to systems and methods for communicating with an ambulatory medical device, such as a drug delivery device, and in particular, a drug pump. In one embodiment, a communication system is provided where a remote drug pump communicates with a similar local drug pump. Each of the drug pumps are provided with a pump controller for controlling operation of the pump. The controller may include a processor and associated memory for storing operating programs and other information. The pumps each include a pumping mechanism controlled by the

controller for pumping fluid to a patient in the normal pumping mode of operation.

Interconnect structure, such as modems, is provided to permit interconnection of the controllers of the pumps in the pump to pump communications mode of operation. The interconnect structure permits communication between the respective processors over a communications medium, such as conventional telephone communication lines. The telephone lines also permit initial voice communication between the patient and the caregiver using conventional telephones or other devices before the pumps are linked together for the pump to pump communications mode of operation. The modems may include speakers to facilitate ease of operation during pump to pump communication with patients who have difficulty in cooperating with the caregiver due to mental and/or physical limitations.

Each drug pump includes operator input structure for making operator inputs to the controller of the respective pump. The operator input structure is useful for selecting desired pump control programs or desired pump data or both from the memory of the processor of the pump. The information selection structure may include a keypad comprising a plurality of keys.

Display structure on each pump is interconnected to the controller of the respective pump. The display structure displays information about operations of the pump sent to the display structure by 5 the controller. The display structure may display desired information from the memory of the processor, such as information relating to the normal pumping operations mode of the pumping mechanism. Other information that may be displayed may relate to various 10 sensor outputs to the controller. Other information displayed may relate to the pump to pump communications mode. The display structure may include an LCD dot matrix display.

Information programmed into the controllers 15 allows the two pumps to communicate in such a way during pump to pump communications that one pump controls the functions of the other. Information programmed into the local drug pump, or caregiver pump, instructs that the caregiver pump be put into the master mode at some point 20 during operation. In the master mode, the local caregiver pump sends its keyboard inputs to a remote patient pump. The caregiver pump also receives its display inputs from the remote patient pump. The caregiver pump is used by the caregiver for such 25 purposes as data gathering, trouble shooting, and operational program changes with respect to the remote patient pump. Ease of communication is provided since the caregiver is likely already familiar with operation

of the patient pump, thereby saving training time because the caregiver pump operates similarly to the patient pump. Further, the caregiver can remain in constant communication with the patient pump by merely 5 transporting the caregiver pump and a modem with the caregiver at all times.

The remote patient pump has information programmed into the controller that instructs the patient pump to be put into the slave mode at the 10 appropriate time. In the slave mode, the patient pump receives its keyboard input signals primarily from the caregiver pump. The patient pump sends its display signals to the caregiver pump. In one embodiment, the slave mode of the patient pump disables the patient pump 15 from actually pumping the fluid during communication with the caregiver pump.

In one embodiment, the caregiver pump and the patient pump both include program means for operating in both the master and slave modes. Automatic selection of 20 the master or slave mode from the normal pumping mode is provided when a communications cable is connected to the respective pump.

Various program means and sequences are disclosed for communication between the local caregiver 25 pump and the remote caregiver pump to facilitate efficient communication while emphasizing easy usage by the caregiver and by the patient, some of whom may have

difficulty carrying out instructions from the caregiver over the telephone.

In another embodiment, systems and methods are provided for communicating between a remote pump and a 5 local caregiver computer, such as a personal computer.

Such communication may permit greater data processing utilizing the computer's data handling capability.

Also, communication with the remote pump using the local computer may be useful for recertifying the remote pump 10 periodically as is sometimes required with respect to medical devices. The local computer may also be useful in changing or adjusting the pump operations program of the remote pump. Modem communication structure permits communication over a communications medium, such as 15 conventional telephone lines, between the remote pump and the local computer.

In a further embodiment, modem communication structure is provided which links a local pump to a local computer. Preferably, the modem communication 20 structure also includes structure for further permitting communication between the local computer or the local pump and a remote pump. This modem communication structure permits: (1) local pump and local computer communication; (2) local pump and remote pump 25 communication; and (3) remote pump and local computer communication.

In another embodiment of the invention, a computer system is provided, with a processor and memory, which is programmed to display an image of a pump on a display that resembles the pump utilized by the patient. The image includes representations of the keys and the display of an actual pump. The computer is further programmed such that the image of the pump is utilized to communicate with an actual remote pump or an actual local pump by manipulating or activating the keys on the image of the pump. The keys of the image can be activated by such techniques as through the use of a mouse or a touch screen. Activating the keys of the image of the pump simulates for the caregiver the presence of an actual pump. This facilitates reductions in training time for training the caregiver to communicate with the patient's pump, since the caregiver is most likely already familiar with operation of the patient's pump.

The computer system with the pump image program may also be used as a simulator for training the caregiver or the patient how to use the pump. The simulator includes various programs for simulating for the patient trainee and/or the caregiver trainee various pump operations situations with a patient's pump for pumping fluid. The simulator also includes various programs for simulating for the patient trainee and/or the caregiver trainee various communication situations with a patient's pump.

These and other features of the present invention are described in greater detail in the detailed description of the preferred embodiments.

5

#### BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, where like numerals refer to like features throughout the several views:

Figure 1 is a schematic diagram illustrating a first system of local pump and remote pump  
10 communications.

Figure 1A is a schematic diagram illustrating components of the remote pump shown in Figure 1.

Figure 2 is a schematic diagram illustrating a second system using a personal computer to communicate  
15 with a local pump and/or a remote pump. Local pump and remote pump communications capability is also shown.

Figure 3 is a schematic diagram of a modem useful in the communication system shown in Figure 2 to interconnect a personal computer, a local pump, and a  
20 remote pump.

Figure 4 is a flow chart of an operational sequence of the patient pump with respect to the normal pumping mode for pumping fluid and the slave mode for pump to pump communication.

25 Figure 5 is a flow chart of an operational sequence of the caregiver pump with respect to the normal pumping mode for pumping fluid and the master mode for pump to pump communication.

Figure 6A and B comprise a single flow chart of operational sequences involving the caregiver pump and the patient pump during connection and communication between the caregiver pump and the patient pump when the 5 patient pump is located at a remote site. Figure 6B follows after Figure 6A during operations.

Figure 7 is a flow chart of operational sequences involving the caregiver pump and the patient pump when the caregiver wants to discontinue 10 communication between the caregiver pump and the patient pump at some time during remote communication between the caregiver pump and the patient pump.

Figure 8 is a flow chart of operational sequences involving the caregiver pump and the patient 15 pump when the patient wishes to speak to the caregiver at some time during remote communication between the caregiver pump and the patient pump.

Figure 9 is a schematic diagram showing a computer screen displaying an image of a pump, as part 20 of a computer system used for communicating with a pump.

Figure 10 is a schematic diagram showing a second computer screen displaying an image of a pump, as part of a computer system, and including information displayed on the screen relating to simulation sequences 25 for use in training.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to Figure 1, a system 10 of communication between a local drug pump 20 (or caregiver pump) and a remote drug pump 40 (or patient pump) is shown. In system 10, local pump 20 is functioning as a caregiver pump for use by the caregiver at the site 32 where the caregiver is located, such as the caregiver's office. Site 32 may be the caregiver's home, during on call periods, or even the caregiver's automobile, if the automobile is provided with some communications capability for sending and receiving signals with respect to another site. In system 10, the caregiver operating pump 20 is typically a nurse, physician, therapist, or other medical personnel.

In system 10, remote pump 40 is functioning as an ambulatory patient pump for pumping drugs to the patient and is located with the patient at a site remote from caregiver pump 20, such as at the patient's home 52. Also, site 52 may be the patient's workplace.

Pumps 20,40 each include a pumping mechanism which is capable of pumping fluid from a fluid reservoir to a patient. Specific components of patient pump 40 are shown in greater detail in Figure 1A. Caregiver pump 20 is preferably identical to patient pump 40 with respect to the features shown in Figure 1A.

Pump 40 as shown in Figure 1A includes a pumping mechanism 43 and a fluid reservoir 47 interconnected by a fluid communication structure 47a, such as a tube. The fluid reservoir 47 may be a 5 cassette mounted to pump 40, or the fluid reservoir may be a container located at a remote site from pump 40, both interconnected to pump 40 with a fluid communication tube 47a. To pump fluid to a patient, the pump is also interconnected to the patient, such as 10 through a tube 40a. The pumping mechanism 43 pumps fluid from the reservoir 47 to the patient through the tube 40a interconnected to the patient.

Pumps 20,40 may be any of a variety of drug delivery pumps. An example of one drug delivery pump is 15 described in U.S. Patent No. 4,559,038, incorporated herein by reference. In U.S. Patent No. 4,559,038, a rotating camshaft is provided which engages two reciprocating valves and a reciprocating expulser. The valves and expulser engage a tube interconnected in 20 fluid communication between a fluid reservoir and the patient. The rotating camshaft moves the valves and expulser to pump fluid through the tube.

In the communication system 10 of Figure 1, only patient pump 40 is utilized to pump fluid to the 25 patient. Caregiver pump 20 is used by the caregiver to communicate with patient pump 40. Caregiver pump 20 is preferably not used to pump fluid during pump to pump communication with patient pump 40. However, caregiver

pump 20 could be used to pump fluid to a patient before or after communication with patient pump 40, should the need arise. In some cases, caregiver pump 20 could be used to pump fluid during pump to pump communications 5 with patient pump 40.

Pumps 20,40 each include a controller for controlling operation of the pumping mechanism utilized to pump fluid. Pump 40 shown in greater detail in Figure 1A includes a controller 41 interconnected to 10 pumping mechanism 43 through connection structure 43a. The controller 41 preferably includes a processor and memory programmable with selected functions for controlling operation of the pumping mechanism 43. As shown in Figure 1A, the controller 41 is also 15 connectable to one or more electrical sensor elements in the pump, such as sensors 45,49.

A variety of sensors like sensor 45 may be provided depending on the type of pump and the intended usage of the pump. For example, since the fluid is 20 pumped through a tube 40a to the patient by the pump, the pump may include a downstream high pressure sensor to detect when an occlusion of the tube has occurred. A sensor may also be provided to sense when a vacuum develops in tube 47a upstream from the pump between the 25 pump mechanism 43 and the fluid reservoir 47, indicating a lack of fluid to be pumped. Other sensors may be provided to sense pump electrical power supply status. Still other sensors may be provided to monitor the

operation of the mechanical components comprising the pumping mechanism. The sensors, like sensor 45, all typically send a suitable electrical signal to the processor of controller 41 through connection structure, 5 like structure 45a, indicative of the conditions sensed. The controller is appropriately programmed to receive and process the sensor signals it receives. Sensor 49 relates a particular sensor useful during pump to pump communications to assist the operators (both patient and 10 caregiver) in communication between the pumps, which will be discussed in greater detail below.

The controller 41 includes memory for storing various programs and data related to operation of the pump. The processor runs the desired operating programs 15 to control operation of the pumping mechanism 43. The processor further responds to the sensor input signals by generating appropriate control output signals in accordance with its programmed control logic. Access to the processor is provided through an external 20 communication port 42. For caregiver pump 20, access to the processor is provided through an external communication port 22 (see Figure 1).

Both caregiver pump 20 and patient pump 40 can be utilized for pumping or delivering a drug to a 25 patient when the respective pump is interconnected to the patient. Pumps 20,40 are preferably identical with respect to the electrical and the mechanical fluid pumping functions. One advantage of this is that

caregiver pump 20 can be an unused spare patient pump

40. As will be discussed below, the respective controllers of pumps 20,40 may be programmed differently to operate in the appropriate desired manner during pump 5 to pump communications. As will also be discussed, this programming can be done locally or remotely.

Preferably, pumps 20,40 include appropriate programs to operate either as a master pump or as a slave pump during pump to pump communications. In some cases, the 10 programs in each pump that control operation of the pumping mechanism will be different. This will also be discussed in more detail below.

One preferred processor that may be used in connection with pumps 20,40 is a MC68HC11E9 high-density 15 complimentary metal-oxides semiconductor (HCMOS) high-performance microcontroller unit (MCU) by Motorola. Such processor includes 512 bytes of electrically erasable programmable ROM (EEPROM), and 512 bytes of RAM.

20 Pumps 20,40 each include operator input structure for permitting an operator of the respective pump to communicate with the controller of the pump, specifically the internal processor of the pump and the information in the internal memory. In one preferred 25 embodiment, a plurality of operator keys 24 on caregiver pump 20 are provided for pressing by the caregiver. Preferably, each key has at least one function. Keys 24 send a signal to the controller of caregiver pump 20

indicative of the key pressed by the caregiver. The controller of pump 20 responds in the desired manner if an acceptable key press is made by the caregiver.

Patient pump 40 has keys 44 preferably 5 identical to keys 24. Keys 44 send a signal to the controller of patient pump 40 indicative of the key pressed. The controller of patient pump 40 responds in the desired manner if an acceptable key press is made by the patient. As shown in Figure 1A, keyboard 44 is 10 interconnected to controller 41 through connection structure 44a.

Caregiver pump 20 includes a display 26 for displaying selected information stored in the controller. In one preferred embodiment, the display 26 15 includes an LCD dot matrix display. LCD dot matrix display 26 is interconnected to the controller of caregiver pump 20. Display signals sent from the controller of caregiver pump 20 permit display of information related to operation of pump 20 on display 20 26. One preferred LCD dot matrix display is a display with four lines and twenty-one characters per line.

Patient pump 40 has a display 46 preferably identical to display 26 of caregiver pump 20. Display signals sent from the controller of patient pump 40 25 display information related to operation of pump 40 on display 46. As shown in Figure 1A, display 46 is interconnected to controller 41 through connection structure 46a.

Communication port 22 of caregiver pump 20 permits interconnection of the controller of caregiver pump 20 to a modem 28 located locally with respect to caregiver pump 20. Caregiver pump 20 is interconnected 5 to modem 28 through connection structure 30, such as an RS232 serial cable. Caregiver pump 20 and modem 28 may be located at the caregiver's office 32, at the caregiver's home during on-call periods, or even at a mobile site, such as the caregiver's automobile.

10 Communication port 42 permits interconnection of the controller of patient pump 40 to modem 48 with connection structure 50, such as an RS232 serial cable. Patient pump 40 and modem 48 are both located remotely to caregiver pump 20 and modem 28, such as at the 15 patient's home or workplace 52, or other location remote from caregiver pump 20.

Communication between pump 20 and pump 40 through modems 28,48 is over communications medium 54 such as conventional telephone lines, cellular phones, 20 fiber optics links, satellite links, microwave links, or other. Modems 28,48 preferably communicate at 9600 bps and include error correction and data compression features over conventional telephone lines.

One advantage of the present invention is that 25 the caregiver can communicate with the patient pump 40 using a similar pump, the caregiver's pump 20. The caregiver presumably has knowledge of operation of patient pump 40. This knowledge is useful in utilizing

caregiver pump 20 to communicate with patient pump 40 to access the processor of patient pump 40 from a remote location.

Communication between the controller of the 5 remote patient pump 40 and the controller of the local caregiver pump 20 permits remote data gathering from the remote patient pump by the local caregiver pump. Such data gathering may be useful for periodic monitoring of the patient pump 40 during use of the patient pump at 10 the remote site. Data gathering may also be useful at the end of the patient use.

Communication between the remote patient pump 40 and the local caregiver pump 20 permits troubleshooting with respect to the remote patient pump, 15 without the caregiver being located at the same location as the patient's pump. Remote troubleshooting is useful in the case where patients are unfamiliar with the some of the more sophisticated operations of their pump. Also, remote troubleshooting using the pump to pump 20 communication system is useful for patients who have difficulty orally communicating with the caregiver over the telephone.

Communication with the remote patient pump 40 is also useful for accessing the pump operations 25 programs for changing or adjusting the operation of the remote patient pump from the local site, thereby saving the caregiver and the patient time from not having to make an in-person visit.

Information programmed into the controller of the caregiver pump 20 permits the caregiver pump 20 to be put into a master mode from the normal pumping mode at the appropriate time. In the master mode, caregiver

5 pump 20 sends a keyboard input signal indicative of a key 24 pressed by the caregiver over port 22 to patient pump 40. In the master mode, caregiver pump 20 receives its display signals primarily from patient pump 40 via communication port 22. In the master mode, the key

10 presses on keys 24 of caregiver pump 20 do not access the memory of caregiver pump 20 for the purposes of programming the memory of caregiver pump 20 or selecting information for display relating to caregiver pump 20.

The master mode is primarily for permitting caregiver

15 pump 20 to communicate with the controller of patient pump 40 for the purposes of programming the memory of patient pump 40 or selecting information for display relating to patient pump 40 from the memory of patient

60 pump 40.

20 With respect to patient pump 40, information programmed into its controller permits patient pump 40 be put into a slave mode from the normal pumping mode at the appropriate time. In the slave mode, patient pump 40 receives keyboard input signals primarily from

25 caregiver pump 20 via communication port 42. Patient pump 40 sends its display signals from communication port 42 to caregiver pump 20.

To communicate between caregiver pump 20 and patient pump 40 over modems 28,48, caregiver pump 20 is out of the normal pumping mode and in the master mode. Similarly, patient pump 40 is out of the normal pumping mode and in the slave mode. In some cases, controllers with sufficient capacity may be provided where the pumps 20,40 operate simultaneously in the normal pumping mode and in the master or slave modes.

In system 10, patient pump 40 is at least 10 programmed to be operable in two modes, the normal pumping mode and the slave mode. There typically is not a need for patient pump 40 to operate in the master mode when the patient possesses the patient pump. Further, in system 10, caregiver pump 20 is at least operable in 15 the master mode. However, situations are anticipated where it is desireable to have one or both pumps 20,40 include programs for operation in the normal pumping mode, the slave mode, and the master mode. In some cases, caregiver pump 20 may be an unused patient spare. 20 At a later date, the unused patient spare may be needed as a patient pump. This would require the slave mode operating program, and a particular normal operation mode program suitable for the patient. It may be more efficient for the caregiver if the controller of each 25 pump 20,40 is preprogrammed to include both the master mode program and the slave mode program. The selection of master or slave mode may be made by the caregiver by preconfiguring the patient's pump 40 to enter the slave

mode during pump to pump communication, and not enter the master mode. The caregiver would have the capability to preconfigure the caregiver pump 20 to only enter the master mode during pump to pump communication, 5 and not the slave mode if the caregiver desired. At some point later in time, the caregiver could reconfigure the caregiver pump 20 to only enter the slave mode during pump to pump communications if the caregiver pump 20 was needed as a patient pump.

10 In system 10 of Figure 1 which shows linking caregiver pump 20 to patient pump 40, the caregiver is able to access the controller of patient pump 40, make various inputs using the caregiver's pump 20, and receive back display inputs from patient pump 40 such 15 that the caregiver can see the display inputs on the display 26 of caregiver pump 20. Such communication can occur when the patient pump 40 is located at a remote site from caregiver pump 20. This is particularly advantageous in saving resources by reducing the number 20 of in-person visits between the caregiver and the patient.

In one embodiment, disabling structure is provided with respect to caregiver pump 20 for disabling the pumping mechanism of caregiver pump 20 such that 25 during pump to pump communications, the pumping mechanism is disabled. Similarly, for patient pump 40, disabling structure is provided to disable the pumping mechanism of patient pump 40 during pump to pump

communications. This may be necessary due to processor capability limitations. This may also be a safety feature to prevent a caregiver from starting operation of the patient's pump from the remote site. However, in 5 some situations it may be desirable for caregiver pump 20 to begin operation of the pumping mechanism of patient pump 40 at a site remote from the location of the caregiver during pump to pump communications. If a suitable controller is provided, it may be possible to 10 operate the pumping mechanism of patient pump 40 while patient pump 40 is communicating with caregiver pump 20.

Referring now to Figure 4, a flow chart 200 is shown illustrating one preferred operational sequence of patient pump 40 with respect to the normal pumping mode 15 and the slave mode. Figure 5 is a flow chart 250 illustrating one preferred operational sequence of caregiver pump 20 with respect to the normal pumping mode and the master mode. Figures 4 and 5 illustrate the operational sequences for each pump with respect to 20 normal pumping operations mode, or pump to pump communications operations mode (slave and master modes). Figures 4 and 5 specifically show the sequences with respect to communicating the key input signals and the display signals between the pumps.

25 Referring now to Figures 6A and 6B, a flow chart 300 is shown for more specific operational sequences followed during connection and communication between caregiver pump 20 and patient pump 40,

respectively. Flow chart 300 of Figures 6A and 6B includes a caregiver sequence 302 in the left hand column and a patient sequence 304 in the right hand column. Flow chart 300 also includes actions to be 5 taken by the patient and the caregiver during connection and communication between the two pumps.

The flow chart 300 of Figures 6A and 6B shows various steps including the step of hitting the ENTER key. The ENTER key is one key of keys 24 on caregiver 10 pump 20 and keys 44 on patient pump 40.

If a caregiver wanted to monitor or program a patient's pump 40 over the phone line 54, the caregiver and the patient would first contact each other, such as by voice communication over the telephone 29,49, as 15 shown in Figure 1, to begin initiation of pump to pump communication. Telephones 29,49 may be conventional telephones including means for dialing another phone, and a handpiece or other device for permitting voice communication with the party on the other end. Prior to 20 initiation of pump to pump communication, both pumps 20,40 are in the normal pumping mode. At the top of each column 302,304 of Figure 6A, pumps 20,40 are in the normal pumping mode. As shown in Figure 6A, the caregiver would first instruct the patient to connect 25 pump 40 to modem 48, thereby automatically stopping the pump and selecting the appropriate processor program for the slave mode.

Automatic selection of the slave mode and stoppage of the normal pumping mode in patient pump 40 is provided using suitable logic circuitry and sensor structure, such as sensor 49 in Figure 1A, to sense the 5 presence of cable 50. Automatic selection of the slave mode and stoppage of normal pumping mode by inserting cable 50 into patient pump 40 is useful since it eliminates one or more keyboard entries that might otherwise be necessary by the patient or caregiver to 10 place patient pump 40 in the slave mode from the normal pumping mode. Alternatively, the patient may have to hit a predetermined key 44 or flip a suitable switch to exit the normal pumping mode and enter the slave mode if no automatic selection of the slave mode and automatic 15 stoppage of the normal pumping mode is provided.

In Figure 1A, sensor 49 is interconnected to communications port 42 through connection structure 49b, and to controller 41 through connection structure 49a. Sensor 49 may include two spaced apart pins which 20 engage the communication cable 50 to close an electrical loop when the cable 50 is operatively positioned in communications port 42. Closure of the loop sends a suitable signal to controller 41 that the cable 50 is present and pump to pump communications is desired, i.e. 25 the slave mode operations program.

The operating system of caregiver pump 20 shall allow the pump to be placed in the caregiver mode of remote programming from the normal pumping mode of operation. Automatic selection of the master mode and 5 automatic stoppage of the normal pumping mode in caregiver pump 20 is provided using suitable logic circuitry and sensor structure to sense the presence of cable 30, such as with a similar sensor to sensor 49 of patient pump 40. Alternatively, the caregiver may have 10 to hit a predetermined key 24 or flip a suitable switch to exit the normal pumping mode and enter the master mode if no automatic selection linked to insertion of cable 30 is provided.

Caregiver pump 20 operating in the master mode 15 includes program means for initiating a modem link to the patient pump 40 operating in the slave mode, as shown in flow chart 300 of Figures 6A and 6B. The phone connection to the patient pump 40 shall be assumed to be open. When the modem link between the pumps is 20 established, each time the caregiver presses a key 26 on caregiver pump 20, a key input signal is sent by program means in the controller of caregiver pump 20 to patient pump 40. Program means in patient pump 40 responds to the signal as if it were a key pressed on its own 25 keyboard. Once the processor of patient pump 40 responds to the key input signal, program means in the controller of patient pump 40 sends the updated display signal to caregiver pump 20.

As shown in Figure 6B, patient pump 40 sends its current display to caregiver pump 20 once the pumps are first linked together. In pump to pump communications, the controllers are preferably menu driven and the current display lets the caregiver see the current status of the patient pump 40 before the caregiver begins to send key input signals to patient pump 40 to obtain the desired information from the patient pump. Following the display on display 26 of 10 the current information on display 46, caregiver pump 20 receives its displays sent to caregiver pump 20 in response to the key inputs to caregiver pump 20 which are sent to patient pump 40.

Instead of an automatic initiation of the modem link to patient pump 40 operating in the slave mode, the caregiver and the patient could both hang up their respective phones after the modem cables were connected. Patient pump 40 is programmed to instruct modem 48 installed at the patient's home to answer the phone the 20 next time it rings. The patient would then wait for the caregiver to call back. Caregiver pump 20 is programmed to instruct modem 28 to call the patient back. Once modem 28 is connected with modem 48, communication between the respective controllers is provided with 25 respect to key input signals and display signals.

In one embodiment, display 46 of patient pump 40 displays everything that is sent to display 26 of caregiver pump 20. In another embodiment, the

controller of patient pump 40 is programmed to include a blocking program to block some or all of the information that is sent to the controller of caregiver pump 20 from the controller of patient pump 40 from being displayed

5 on display 46 of patient pump 40 during pump to pump communication. This may be advantageous in keeping some information from the patient, such as controller access codes used to access the processor of patient pump 40 via the keys 44, or keys 24 during pump to pump

10 communications.

If the communication session were interrupted by a bad phone line, patient pump 40 might remain unchanged or partially programmed. During programming of patient pump 40, caregiver pump 20 could get a

15 continuously updated status report from patient pump 40 through appropriate programming in caregiver pump 20 and patient pump 40. The caregiver could review the status report after disconnecting the pump from the modem to verify that patient pump 40 had been programmed as

20 desired by the caregiver.

The controller of each pump 20,40 controls operation of the respective modem 28,48 attached as a peripheral device. The controller of each pump 20,40 instructs its respective modem to go off-hook and

25 disconnect the phone at the initiation of pump to pump communications. The controllers further control operation of a modem speaker associated with each modem so that the patient and caregiver can orally communicate

before pump to pump communication begins, and after the voice transmitting and receiving characteristics of one or both of the telephone hand piece have been terminated. The modem speakers are useful if the

5 patient or caregiver is not using the telephone handpiece and such communication is desired. The one party can call to the other through the speaker to pick up the telephone handpiece. Also, the modem speaker lets the caregiver hear predetermined signals from the

10 patient pump 40 during connection to let the caregiver know when the patient pump 40 is ready to begin pump to pump communication, as shown in the flow chart of Figures 6A and 6B.

The controller of each pump 20,40 may be

15 provided with masking programs to mask the keys 24,44 which are inactive during pump to pump communication.

Referring now to Figure 7, a flow chart 400 of a caregiver initiated disconnect operational sequence is shown for disconnecting caregiver pump 20 from patient pump 40. Such disconnect operational sequence is desirable when the caregiver no longer desires communication with patient pump 40. In the flow chart 400 of Figure 7, a caregiver sequence 402 is shown in the left hand column and a patient sequence 404 is shown

20 in the right hand column. Flow chart 400 describes the various steps during the disconnect sequence initiated by the caregiver. At the top of each column 402,404 of

Figure 7, pumps 20,40 are in the master and the slave modes, respectively.

Attempting to start the caregiver pump 20 is one method of signalling to the controller to terminate 5 the pump to pump communication. The controller of caregiver pump 20 begins the disconnection sequence with respect to modem 28. The controller of caregiver pump 20 further requests that patient pump 40 begin the disconnection sequence with respect to modem 48.

10 The operating system of each controller allows for automatic disconnection of the respective modems at the conclusion of pump to pump communication, as shown in Figure 7. The controllers further control operation of the modem speaker so that the patient and the 15 caregiver can orally communicate after pump to pump communication, such that the caregiver can instruct the patient during the disconnect procedures prior to telephone voice communication through the telephone handpiece of the patient.

20 Program means is provided with patient pump 40 to control operation of a beeper, other sound alarm, or other pump to patient indicator to inform the patient of the upcoming disconnection, as noted in flow chart 400 of Figure 7. The beeping or other signal may continue 25 until the disconnection is complete. This is useful in informing the patient when the pump to pump communications disconnection procedure begins and when

it ends such that the pump is ready to be used in the normal pumping mode.

Referring now to Figure 8, a flow chart 500 for a patient initiated disconnect operational sequence is shown. The flow chart of Figure 8 shows a caregiver sequence 502 in the left hand column and a patient sequence 504 in the right hand column. At the top of each column 502,504 of Figure 8, pumps 20,40 are in the master and slave modes, respectively.

10 In the flow charts of Figure 7 and 8, it is noted that the caregiver and the patient press the STOP/START key. The STOP/START key is another one of the keys on keys 24,44 of pumps 20,40. If the pumps are not in the normal pumping mode during pump to pump 15 communication, as is the case in one embodiment, then the STOP/START key is a convenient means for sending a signal to the respective controllers that a discontinuation of the pump to pump communications session is desired by the patient or the caregiver.

20 As shown in Figure 8, attempting to start patient pump 40 using the STOP/START key on patient pump 40 is a one method of signalling to the processor to terminate the pump to pump communication. Patient pump 40 requests that caregiver pump 20 begin the 25 disconnection sequences. Patient pump 40 waits for caregiver pump 20 to initiate the disconnect process. The controller of caregiver pump 20 begins disconnection with modem 28, and the controller of caregiver pump 20

further requests that controller of patient pump 40 begin the disconnection sequence with respect to modem 48. It is to be appreciated that when patient pump 40 receives a key input signal from the patient to begin 5 disconnection of the pump to pump communications connection, caregiver pump 40 may continue until caregiver desires to terminate the pump to pump communications connection. The caregiver presses a key, such as the STOP/START key, as noted in Figure 8 to 10 begin the disconnection sequence at the desired time.

As in the caregiver disconnect sequence of Figure 7, the disconnect sequence of Figure 8 includes the controllers controlling operation of the modem speakers so that the patient and the caregiver can 15 orally communicate after pump to pump communication, so that the caregiver can instruct the patient during the disconnect procedures prior to telephone voice communication through the handpieces.

Program means is provided with patient pump 40 20 to control operation of a beeper or other sound alarm or patient indicator to inform the patient of that the disconnection requested by the patient is upcoming, as noted in flow chart 500 of Figure 8. The beeping or other signal continues until the disconnection is 25 complete. The audible or other patient signal may be used in combination with or in alternative to the use of the modem speaker at the patient site to indicate to the

patient when the cable 50 is to be disconnected from patient pump 40.

Program means is provided with caregiver pump 20 to control operation of a beeper or other sound alarm 5 or caregiver indicator to inform the caregiver that the disconnection has been requested by the patient. This is a page type function where the caregiver can continue with pump to pump communication, or start the disconnect sequence by pressing the STOP/START key.

10 In some applications, the controller of patient pump 40 is locked, at least partially, via an access code program to prevent the patient from altering the pump operations program or from accessing other information in the memory. In one preferred embodiment, 15 the caregiver can unlock the pump lock of patient pump 40 from a remote location via the pump to pump communication system. Preferably, the caregiver can then relock the pump lock of patient pump 40 after the caregiver has adjusted or changed the pump operations 20 program. Automatic relock program means may be provided to automatically relock the controller at the conclusion of the caregiver's access of the controller to change the operating programs.

Referring now to Figure 2 where an alternative 25 embodiment is shown, the schematic diagram illustrates a communication system 60 for communication between pump 62 and a computer 80, both located at caregiver's office

66. Pump 62 may be a caregiver pump, like caregiver pump 20, or a patient pump, like patient pump 40.

Figure 2 also illustrates communication between a patient pump 64, located at the patient's home 68, and 5 both computer 80 and pump 62. It is to be appreciated that in some applications, pump 62 may not be present. Also, it is to be appreciated that in some applications pump 64 may not be present. In either of those applications, computer 80 would be communicating only 10 with the remaining pump.

An example of computer 80 includes an 80386 INTEL microprocessor, with 2 megabytes of RAM and operated by commercially available operations software such as DOS, UNIX, and others and further programmed 15 with application specific program functions to communicate with pumps 62,64 and carry out the specified tasks desired by the caregiver. A suitable keyboard may be provided with computer 80 to make operator inputs to the microprocessor.

20 As shown in Figure 2, computer 80 may further communicate with a second computer 86 to transfer data and or programs to and from computer 80 over communications medium 87, such as conventional telephone lines. For example, computer 80 may be located at the 25 caregiver's office 66, such as a hospital. The second computer 86 may be located at the pump manufacturer's/servicer's facilities 88. The second computer may receive and transmit information to a

plurality of computers 80. This arrangement may be useful for maintaining a plurality of patient pumps 64, through a plurality of caregiver's offices 66. Also, improved drug therapies may result if the pump 5 manufacturer/servicer has ready access to patient pump usage data.

Pumps 62,64 are preferably identical mechanically and electrically to pumps 20,40 described previously. In some situations, the controllers of 10 pumps 62,64 may be programmed differently, depending on how the pumps are to be used. Pump 64 is typically used as a patient pump. As a patient pump, pump 64 requires the normal pumping mode operating program and the slave mode operating program at minimum.

15 In system 60, pump 62 may be a patient pump or a caregiver pump. As a patient pump, pump 62 requires the normal pumping mode operating program and the slave mode operating program at a minimum. Pump 62 as a patient pump is present at the same site as computer 80 20 such as when pump 62 is brought in by the patient. In some situations, pump 62 may be a patient pump that is in the caregiver's office 66 for data gathering, trouble shooting, and/or program changes or modifications.

Also, before the patient leaves the caregiver's office 25 66, pump 62 is present in caregiver's office 66 for use as a patient pump in the caregiver's office. As a caregiver pump, pump 62 requires the master mode operating program at a minimum. Pump 62 operating as a

caregiver pump may also include the normal pumping mode operating program and the slave mode operating program.

To permit communication between pump 62, computer 80, and pump 64, a modem 100 is provided.

- 5 Referring now to Figure 3, modem 100 is shown in additional detail. Modem 100 includes a local pump communications cable 102 for electrical connection of modem 100 to a local pump such as pump 62 shown in Figure 2. Cable 102 is like cables 30,50 of Figure 1.
- 10 Cable 102 extends from modem controller 110 for selective connection to pump 62.

Modem 100 further includes a computer communications port 104 for electrically linking modem 100 with computer 80 as shown in Figure 2.

- 15 Modem 100 further includes a phone system communications port 106 for electrically linking modem 100 to remote sites over communications medium 54. In the embodiment shown, communications port 106 permits interconnection of modem 100 with modem 48 over the
- 20 telephone lines 54, as shown in Figure 2. Such interconnection permits communication between modem 100 and patient pump 64, located at a remote site from modem 100.

Modem 100 further includes a local phone

- 25 communications port 108 to permit interconnection of a local phone (not shown) with modem 100. Local phone port 108 permits use of a local phone such that the caregiver can communicate by conventional telephone

voice communication with the patient, before a modem link is established and after the modem link is terminated.

Modem 100 permits information to be transmitted 5 from computer 80 to a remote site over the phone lines 54. Modem 100 further permits pump 62 to communicate with the remote site over phone lines 54. Remote communication with pump 64 over the phone lines through modem controller 110 and modem module 112 is preferably 10 at 9600 bps (bits per second). Modem 100 preferably includes error correction and data compression capabilities.

Modem 100 further permits communication between pump 62 and computer 80. Preferably, such communication 15 is at 19,200 bps through the modem controller 110 in a pass through configuration. Pump 62 is preferably not linked directly to computer 80, since pump 62 may be provided with different power supplies other than conventional 110 volt power supplies used to power 20 computer 80. Also, it is desireable to electrically isolate pump 62 from computer 80 to protect pump 62 and the patient from hazards of the electrical source powering computer 80, such as electrical shock.

Preferably, modem 100 communicates with computer 80 25 through appropriate connection structure, such as an RS232 serial cable.

Figure 2 also shows pump 62 interconnected to its own stand alone printer 72 interconnected with connection structure 74, such as an RS232 serial cable. Parallel communication may be used, instead of serial 5 communication. Printer 72 produces a hard copy of information stored in the controller of pump 62. In some cases, printer 72 would be useable only through the communications port which connects pump 62 to modem 100, as shown in Figure 2. In other words, pump 62 may not 10 be useable simultaneously with printer 74 and modem 100. An appropriately sized controller and two communications ports would permit such usage.

Communication between computer 80 and a pump, whether remotely (with pump 64) or locally (with pump 15 62) is useful for several reasons. First, computer 80 may be provided with greater memory and data processing capabilities than exist with the individual pumps 62,64. Printing capabilities may be greater with a printer 82 electrically interconnected to computer 80. Display 20 capabilities may be greater with a monitor 84 electrically interconnected to computer 80. Also, computer 80 may be useful in the recertifying operations of the pumps periodically, as required to verify operability and accuracy of the pumps.

25 Computer 80 also may be useful for making program adjustments or application changes in the pumps 62,64. For example, drug delivery devices may be used in a variety of normal pumping modes, or applications,

such as 1) pain control; 2) nutrition; 3) chemotherapy; and 4) antibiotic therapy. Other applications are possible.

Each of the applications may involve different 5 operations of the pumping mechanism. Each application may have one or more patient specific variations on operation of the pumping mechanism and other pump control functions. Also, some of the applications may involve some patient input, such as is sometimes the 10 case in pain control applications. For example, if the patient is experiencing pain at a particular time, the caregiver may provide for increased dosages as needed by the patient, within specified parameters such as time and amount. In this application, the pumping mechanism 15 needs to be operable automatically, and at the discretion of the patient, within the specified parameters. The operating program contains the appropriate pump control commands for controlling the pumping mechanism and the functions of the keys which 20 permit patient control of the pumping mechanism. The other applications may include different pump control commands and different functions of the keys. Within each of the four applications listed above, various 25 different pump operations programs may exist. The controller of the patient pump 40 may be appropriately programmed by the caregiver for the specific patient usage.

It is to be appreciated that the caregiver pump 20 and the patient pump 40 do not need to include the same application program for operating the pumping mechanism. A significant advantage of the present

5 invention is that the caregiver can communicate successively with different patients, with each patient involving a different pump application, or each patient involving the same pump application with different patient specific functions. At a minimum, it is

10 preferred that caregiver pump 20 includes the master mode operations program, and that patient pump 40 includes the slave mode operations program and one application or normal pumping mode operations program for operating the pumping mechanism to pump fluid to the

15 patient. Preferably, it is more convenient for the caregiver if caregiver pump 20 and patient pump 40 include both the slave mode operations program and the master mode operations program, and also at least one normal pumping mode operations program.

20 It is anticipated that the caregiver can locally or remotely program the controllers of pumps 20,40,62,64 such that the pump operates either in 1) the normal pumping mode or slave mode, or 2) the normal pumping mode or the master mode at the initiation of the

25 pump to pump communications sequences.

Various pump related data may be stored in the controllers of pumps 20,40. Information which may be gathered during use of patient pump 40 includes date and time of:

- 5           1) Pump Error Conditions, for example, where the pumping mechanism has stopped and a suitable sensor sends a pump stoppage signal to the processor.
- 2) High Pressure Alarm for Downstream Blockages, where a suitable pressure sensor sends a high pressure signal to the processor.
- 10          3) Upstream Occlusion Alarm, where a suitable pressure sensor sends an occlusion signal to the processor.
- 4) Any Fluid Reservoir Removal Event, where a suitable sensor sends a reservoir removed signal to the processor.
- 15          5) Any Fluid Reservoir Attached Event, where a suitable signal is sent to the processor by a suitable sensor, possibly the same sensor as the sensor for sensing a reservoir removed event.
- 6) Any Internal Battery Event, where a suitable sensor senses whether the battery has been changed, is low, or is depleted.
- 7) Any AC Adaptor Event, where a suitable sensor senses whether the adapter is connected, disconnected, or unplugged from the wall outlet.

- 8) Any portable Power Pack Event, where a suitable sensor senses whether the power pack is connected, disconnected, or depleted.
- 9) Any Remote Dose Cord Event (which permits 5 patient to remotely press a key, such as the DOSE key on the keypad), where a suitable sensor senses whether the dose cord is connected or disconnected.
- 10) Any Communications Cable Event (to permit the pump to communicate with a printer, another pump or 10 a computer), where a suitable sensor senses whether the cable is connected or disconnected.
- 11) Anytime the Device is Successfully Stopped or Started with START/STOP key, where a suitable sensor senses whether the pump is successfully stopped or 15 started after the key is pressed.
- 12) Any Lock Level Change and the New Lock Level, in situations where the amount of access to the processor by the patient is changed, i.e. full access, some access, no access.
- 20 13) Any Patient Pump Operational Program Change or Status Reset/Clear in the New Program.
- 14) Anytime the PRIME key is used and how much fluid is primed to get air out of the pump, such as during pump start up.
- 25 15) Any Patient Dose Delivered and the Amount Delivered by the patient hitting the DOSE key to manually give the patient an additional amount of fluid.

16) Any Change in Other Features (units, time or date set, auto lock change, application change) and the New Data or State.

17) Anytime the Pump is Successfully Recertified.

18) Number of Activations of Pumping Mechanism and Duration of Use.

Various functions are anticipated for each of the keys on each pump 20,40. Each key has at least one 10 function. Examples of potential functions of the different keys include:

1) A NEXT SCREEN key to move through the various screens by running a next screen program;

15 2) An ENTER/CLEAR key;

3) AN UP ARROW key and a DOWN ARROW key for paging through what is displayed on the screen with a highlight bar, or to page through numeric values to highlight and/or display the desired value;

20 4) A PRIME key to run a pump prime program to prime the pump;

5) A START/STOP key for operating a pump start program and a pump stop program;

25 6) A LOCK key for providing access control to the processor through an access program;

- 7) A DOSE key to run a patient pump control program for permitting patient control of the pumping mechanism;
- 8) A HELP key for providing help information on the display.

5 Referring now to Figure 9, a monitor or computer screen 90 is shown, as another embodiment of the invention. An image of a pump 92 (front view) is displayed on screen 90 through suitable graphics 10 capability. Screen 90 is operatively interconnected with a processor of computer system, such as the processor of computer 80. The image 92 on screen 90 is able to be manipulated as if it were a pump through the use of a screen interactive program utilizing a mouse or 15 a touch screen. Computer 80 is programmed to run various programs depending on how the various keys 94 of pump image 92 are pressed through the use of the mouse or the touch screen. This permits simulation of the pump 20 with the use of a computer 80. Display area 95 20 may then display information like display 26 of pump 20.

Computer screen 90 and computer 80 are utilized to communicate with a pump located at a remote site, like pump 64 of Figure 2. If the pump is located locally, like pump 62 of Figure 2, then communication is 25 direct with a straight through pass as shown in Figures 2 and 3.

The arrangement involving the computer screen of Figure 9 is useful when the caregiver is communicating with a patient pump at a remote location or at a local location. The caregiver can more easily 5 use the computer system since the caregiver is already familiar with the operation of a pump through the use of the keys and the display. Activating the keys 94 of the image 92 and using the display 95 of the pump image simulates for the caregiver the presence of an actual 10 pump. This facilitates reductions in training time for training the caregiver to communicate with the patient's pump, since the caregiver is most likely already familiar with operation of the patient's pump.

The computer system with the pump image program 15 may also be used as a simulator for training the caregiver and/or the patient how to use the pump. The simulator includes various programs for simulating operation of a patient's pump to pump fluid. The simulator also includes various programs for simulating 20 various communication situations with a patient's pump.

As shown in Figure 10, a computer screen 96 of a training simulator system is shown. On computer screen 100, pump image 92 and simulator information 98 are displayed. Simulator information is used to select 25 various conditions through simulator programs for simulating a operation of a patient pump. Pump 92 could function as a caregiver pump to permit training of a caregiver on how to use the caregiver pump to

communicate with a patient pump. For example, if the caregiver trainee wanted to simulate a communications session with a remote patient pump that had a low battery, for example, the caregiver trainee would select 5 the program in listing 98 that would simulate a pump to pump communications situation where the caregiver would trouble shoot the patient pump to determine that a low battery situation existed. The simulator also has a simulator program for simulating at least some of the 10 sequences to connect and disconnect the pumps according to the flow charts of Figures 6A, 6B, 7, and 8.

The simulator system also includes simulation programs in information 98 for simulating operation of the pump on the screen 96 as a patient pump to pump 15 fluid to a patient. This would be useful for training a patient and a caregiver how to operate the pump in the normal pumping mode.

The present invention relates specifically to a pump communication simulator for training a pump 20 operator comprising: a computer system including processor means, and display means electrically interconnected to the processor means of the computer system; first program means for displaying an image of the pump on the display means, the image having an input 25 region and a display region; second program means for permitting manipulation of the input region of the image of the pump on the display means by the pump operator such that access to the processor means of the computer

system is achieved; and third program means for sending a predetermined message to the display region of the image of the pump in response to manipulations of the input region of the image by the pump operator.

5 The invention is not to be construed as to be limited by the specific embodiments described above or shown in the drawings, but is to be limited only by the broad general meaning of the following claims.

WHAT IS CLAIMED IS:

1. A pump to pump communication system comprising:
  - (a) first and second pumps, each of the first and second pumps including:
    - (i) means for pumping fluid;
    - (ii) control means for controlling operation of the means for pumping fluid;
    - (iii) operator input means for making an operator input of information to the control means; and
    - (iv) display means for displaying information from the control means;
  - (b) a first modem electrically interconnectable with the control means of the first pump; and
  - (c) a second modem electrically interconnectable with the control means of the second pump, the first and second modems permitting remote communication between the control means of the first pump and the control means of the second pump over a communications medium.
2. The communication system of claim 1, wherein the controller of each pump includes a processor and associated memory.

3. The communication system of claim 1, further comprising:

(a) first communication means for sending an input signal from the control means of the first pump over the first and second modems to the control means of the second pump indicative of an operator's input at the operator input means of the first pump; and

(b) second communication means for sending a display signal from the control means of the second pump over the first and second modems to the control means of the first pump indicative of a display signal sent by the control means of the second pump to the display means of the second pump.

4. The communication system of claim 3, further comprising:

(a) third communication means for sending an input signal from the control means of the second pump over the first and second modems to the control means of the first pump indicative of an operator's input at the operator input means of the second pump; and

(b) fourth communication means for sending a display signal from the control means of the first pump over the first and second modems to the control means of the second pump indicative of a display signal sent by the control means of the first pump to the display means of the first pump.

5. The communication system of claim 1, wherein each of the first and second pumps includes disabling means for disabling the means for pumping fluid during communication between the control means of the first and second pumps.

6. The communication system of claim 1, further comprising a computer system including a processor with associated memory, display means interconnected to the processor of the computer system for displaying information from the processor of the computer system, and keyboard input means interconnected to the processor of the computer system for inputting information to the processor of the computer system; and wherein the first modem includes means for permitting communication between the processor of the computer system and the controller of the first pump, and wherein the first modem includes means for permitting communication between the processor of the computer system and the controller of the second pump over the communications medium.

7. The communication system of claim 3, further comprising display disabling means for selectively preventing display of information from the control means of the second pump on the display means of the second pump.

8. The communication system of claim 3, further comprising:

- (a) a cable for electrically interconnecting the second modem to the second pump; and
- (b) a sensor means associated with the second pump for sensing when the cable is electrically interconnected to the second pump and for sending a signal to the control means of the second pump indicative of the presence of the cable.

9. A pump to pump communication system comprising:

(a) first and second pumps, each of the first and second pumps including:

(i) pump means for pumping fluid;

(ii) processor means including:

(A) means for controlling operation of the pump means;

(B) means for storing predetermined pump data;

(iii) operator input means for making an operator input of information to the processor means; and

(iv) display means for displaying information from the processor means; and

(v) sensor means for obtaining predetermined pump data and for sending the predetermined pump data to the means for storing in the processor means;

(b) modem interconnect means associated with the processor means of the first pump and the processor means of the second pump for permitting communication between the processor means of the first pump at a first location and the processor means of the second pump at a second location remote from the first location over a communications medium;

(c) first input signal program means associated with the processor means of the first pump for sending an operator's input signal from the operator input means of the first pump to the second pump over the modem interconnect means;

(d) second input signal program means associated with the processor means of the second pump for receiving the operator's input signal from the first pump;

(e) first display signal program means associated with the processor means of the second pump for sending a display signal from the processor means of the second pump to the first pump over the modem interconnect means; and

(f) second display signal program means associated with the processor means of the first pump for receiving the display signal from the second pump.

10. The communication system of claim 9, wherein the modem interconnect means includes first and second modems, and first and second modem cable means for electrically connecting the respective first and second modems to the respective first and second pumps, and wherein the sensor means associated with each of the first and second pumps includes first sensor means for sensing when the respective first and second modem cable means is electrically interconnected to the respective first and second pumps and for sending a signal to the means for storing in the processor means of the respective first and second pumps indicative of the presence of the respective first and second modem cable means.

11. The communication system of claim 9, wherein the modem interconnect means includes first and second modems, the first and second modems each including a speaker adapted for voice communication between the modems, and further comprising first and second telephones electrically interconnectable to the respective first and second modems.

12. The communication system of claim 9, further comprising disabling program means associated with the second pump for disabling the pump means of the second pump during communication of the first and second pumps over the modem interconnect means.

13. The communication system of claim 10, further comprising audible signal means for signalling to the operator of the second pump when the operator of first pump desires the operator of the second pump to disconnect the modem cable means connected to the second pump.

14. A pump communication system comprising:

- (a) a pump including:
  - (i) means for pumping fluid;
  - (ii) pump processor means for controlling operation of the means for pumping fluid;
- (b) a computer system including processor means, and display means electrically interconnected to the processor means of the computer system;
- (c) first program means for displaying an image of the pump on the display means;
- (d) second program means for permitting manipulation of the image of the pump on the display means such that access to the processor means of the computer system is achieved; and
- (e) communication means for permitting communication between the processor means of the computer system and the pump processor means.

15. A method of communicating between a first pump and a second pump comprising the steps of:

(a) providing the first and second pumps, each of the pumps including:

(i) pump means for pumping fluid;  
(ii) processor means including associated memory for controlling operation of the pump means;

(iii) operator input means for inputting information to the processor means;

(iv) display means for displaying information from the processor means;

(b) connecting a first modem to the processor means of the first pump;

(c) connecting a second modem to the processor means of the second pump;

(d) interconnecting the first modem with the second modem over a communications medium;

(e) sending an operator input signal from the operator input means of the first pump to the processor means of the second pump;

(f) sending a display signal from the processor means of the second pump responsive to the operator input signal to the processor means of the first pump;

(g) displaying the display signal from the second pump on the display means of the first pump.

16. The method of claim 15, further comprising the step of disabling the pump means of the second pump prior to receiving the operator's input transmitted from the first pump.

17. The method of claim 15, further comprising sending an audible signal to an operator of the second pump when the operator of the first pump desires to terminate communication between the first pump and the second pump.

18. The method of claim 15, further comprising the steps of:

(a) before step (e) of claim 15, transmitting a first voice message between first and second telephone handpieces, the first and second telephone handpieces electrically interconnected to the respective first and second modems during transmission of the first voice message;

(b) after step (g) of claim 15, sending a second voice message between the first telephone handpiece and a modem speaker, the modem speaker electrically interconnected to the second modem during transmission of the second voice message.

19. The method of claim 16, further comprising the steps of:

(a) before step (e) of claim 15, providing:

(i) first and second telephone handpieces electrically interconnectable to the respective first and second modems; and

(ii) first and second modem speakers electrically interconnectable to the respective first and second modems;

(b) before step (e) of claim 15, electrically interconnecting the telephone handpieces to the respective first and second modems to permit voice communication over a communications medium;

(c) before step (e) of claim 15, electrically disconnecting the telephone handpieces from the respective first and second modems;

(d) before step (e) of claim 15, electrically interconnecting the modem speakers to the respective first and second modems to permit voice communication over the communications medium;

(e) before step (e) of claim 15, electrically disconnecting the modem speakers from the respective first and second modems;

(f) after step (g) of claim 15, electrically interconnecting the modem speakers to the respective first and second modems to permit voice communication over the communications medium;

(g) after step (g) of claim 15, electrically disconnecting the modem speakers from the respective first and second modems; and

(h) before step (g) of claim 15, electrically interconnecting the telephone handpieces to the respective first and second modems to permit voice communication over the communications medium.

FIG. 1

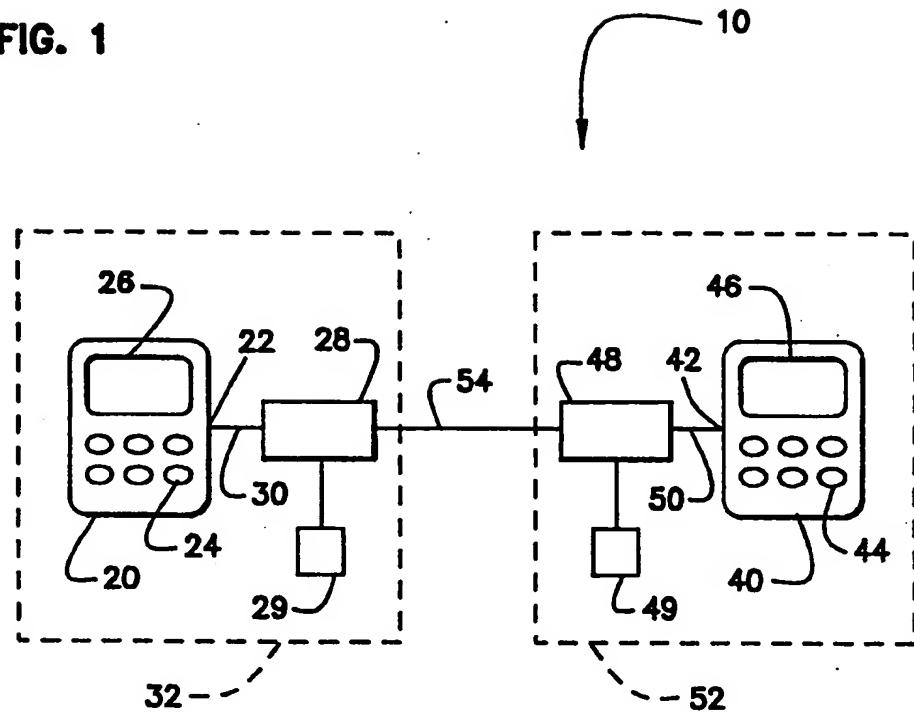


FIG. 2

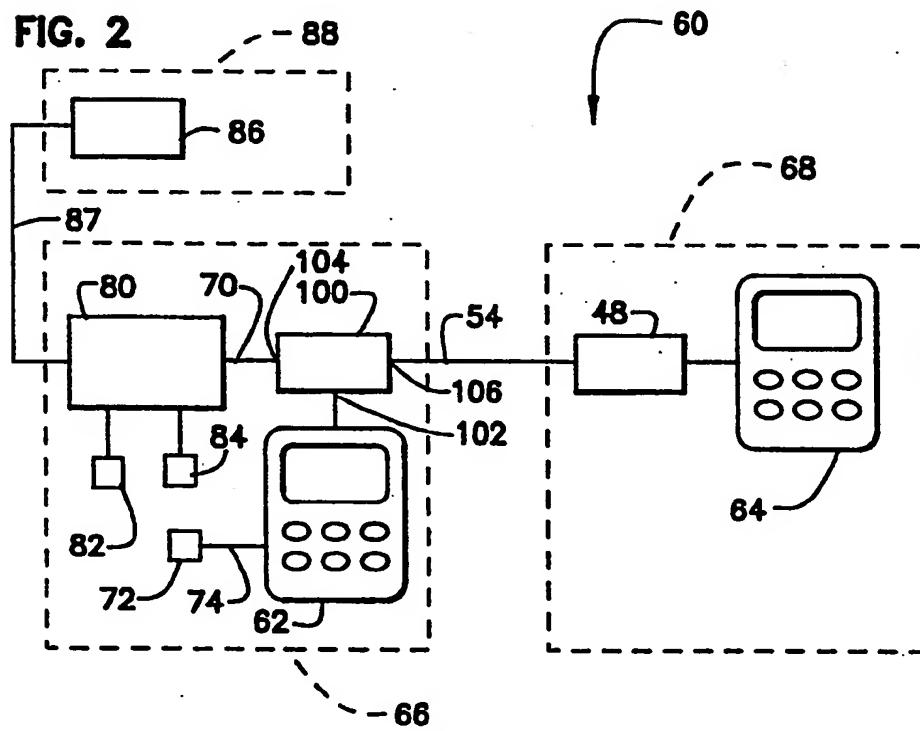
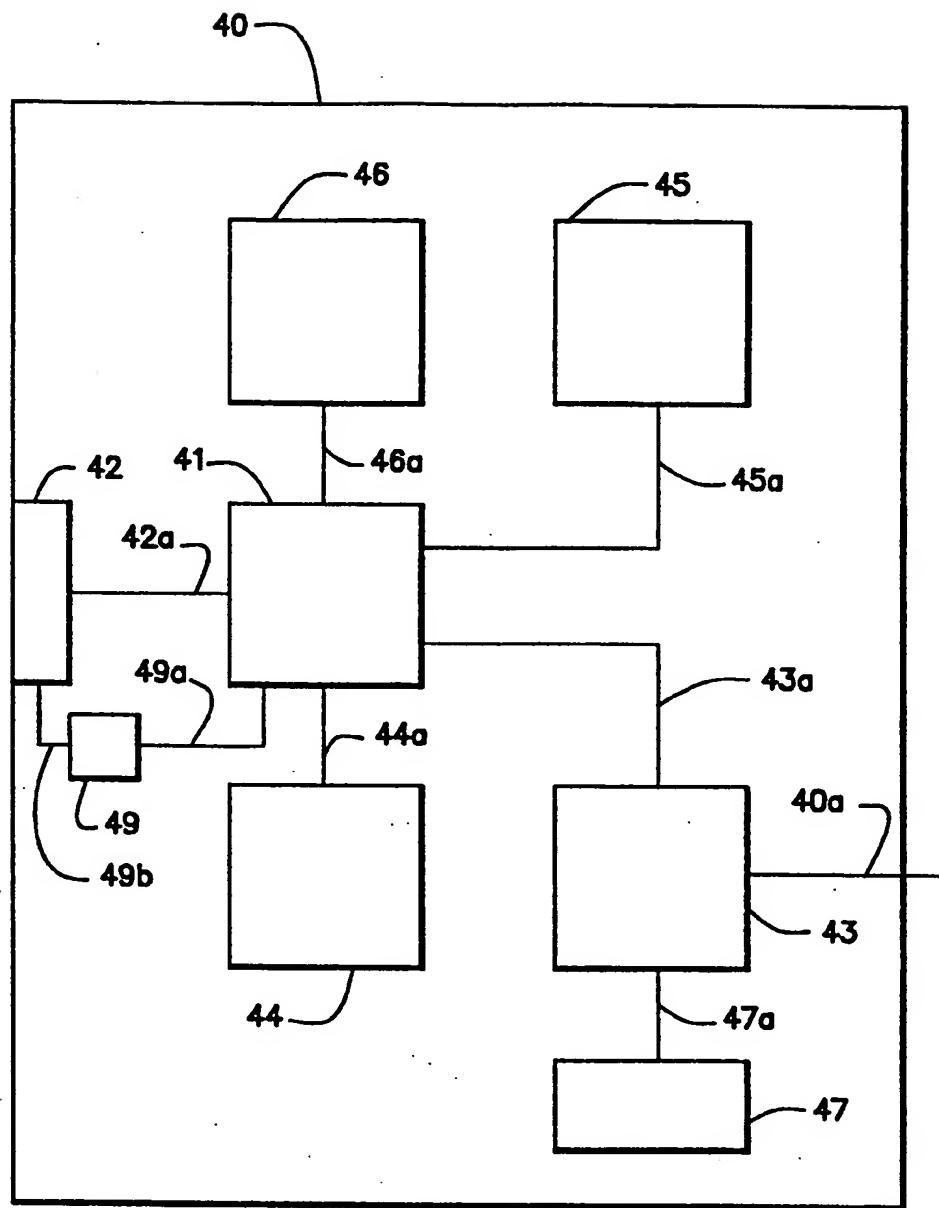
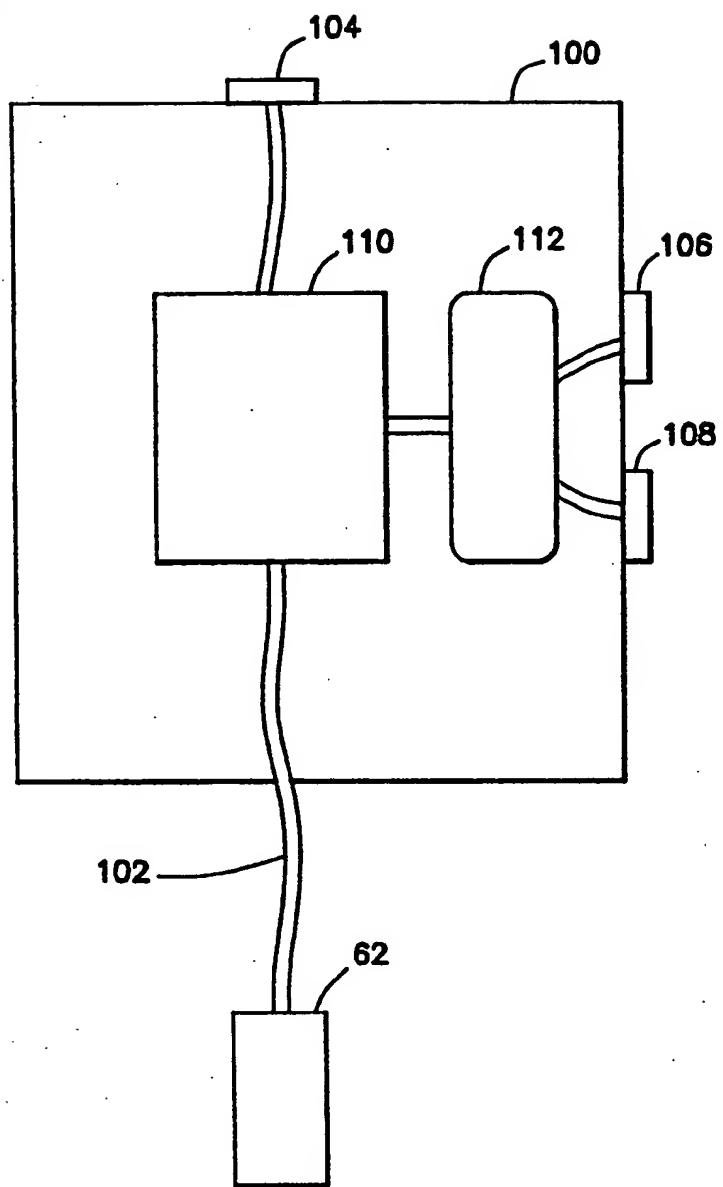


FIG. 1A



**FIG. 3**

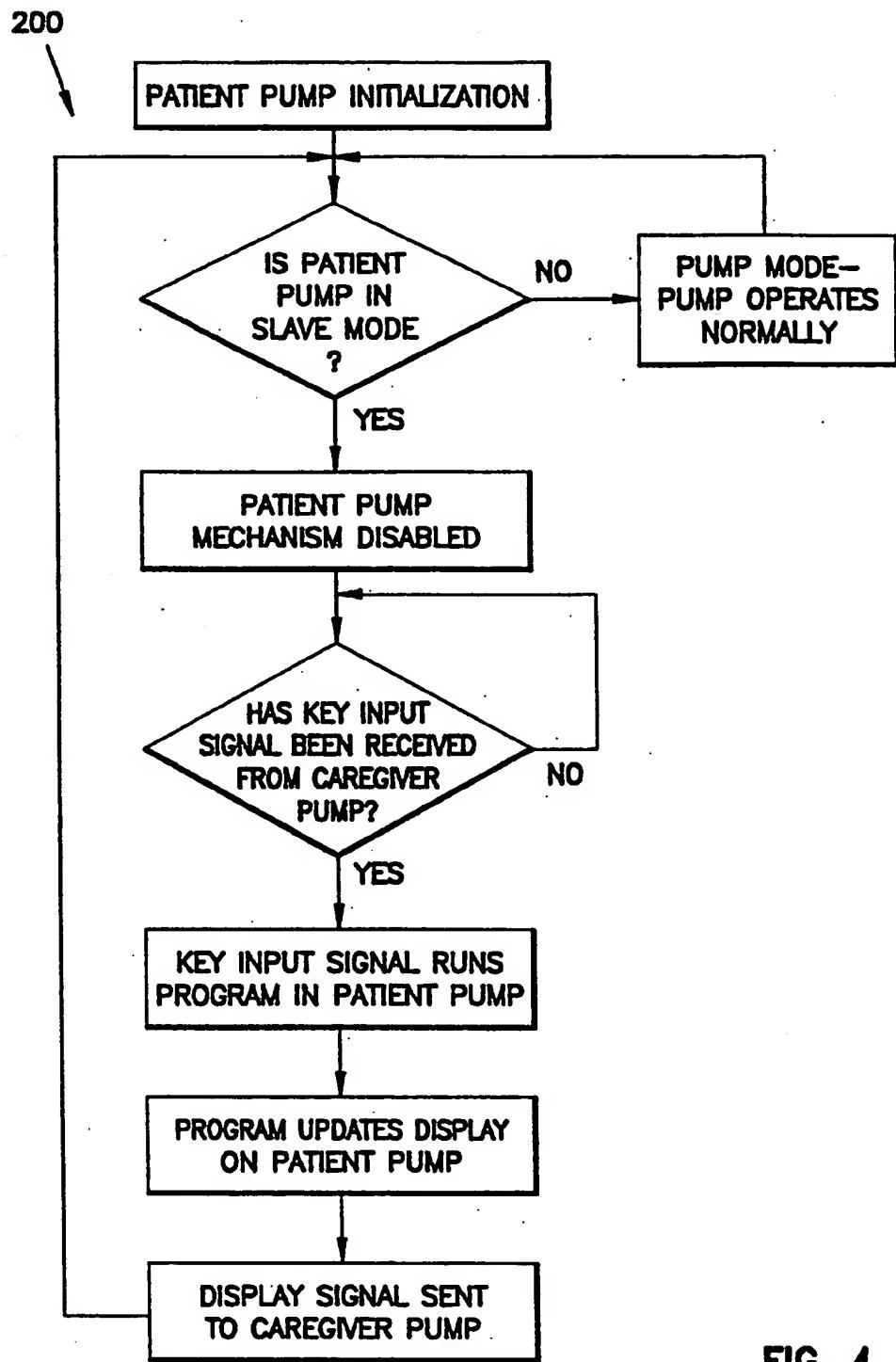


FIG. 4

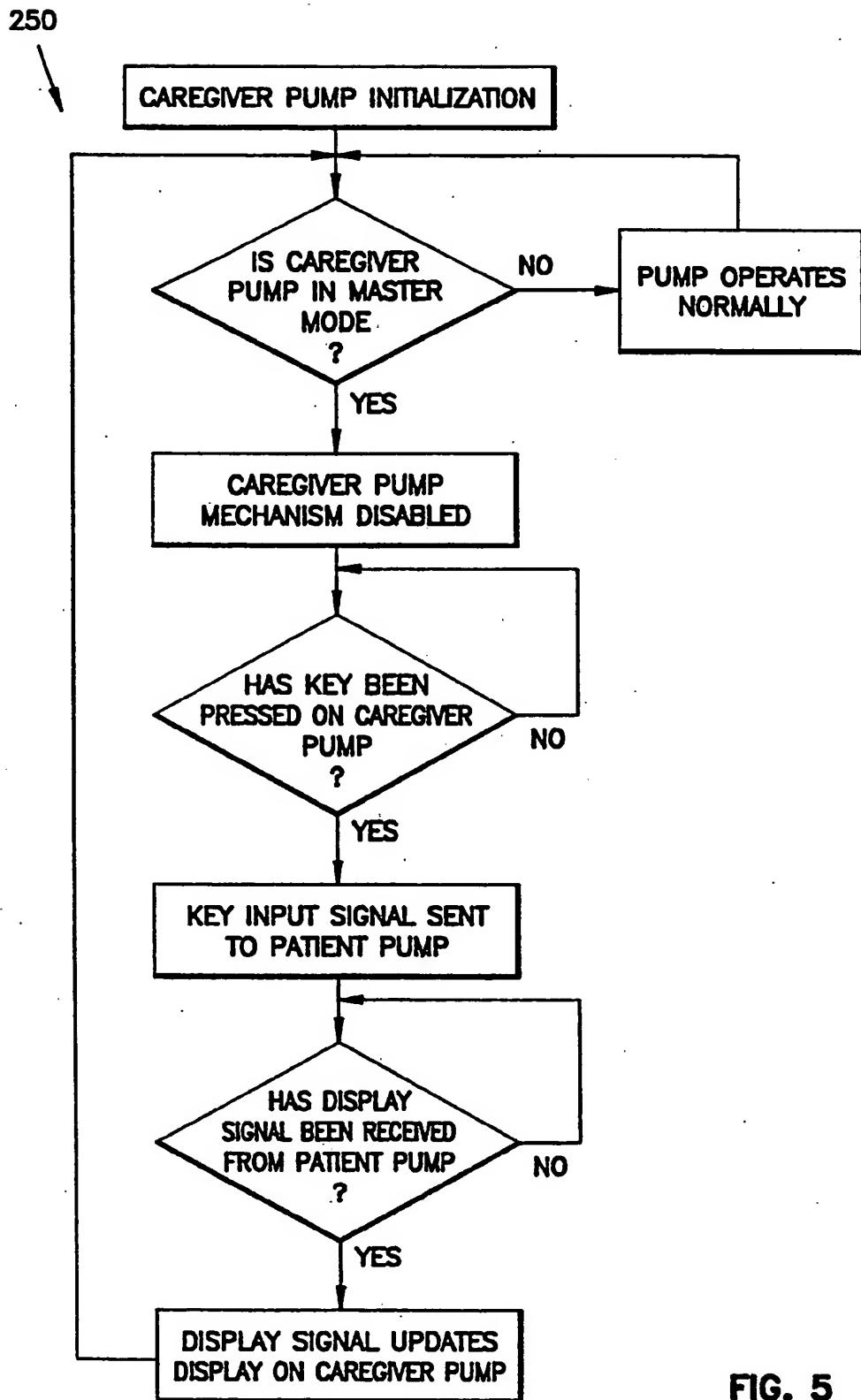
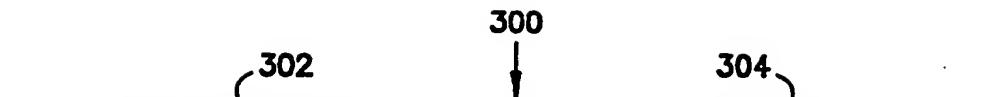


FIG. 5

6 / 10



CAREGIVER PUMP	PATIENT PUMP
CAREGIVER CONNECTS CAREGIVER MODEM CABLE TO CAREGIVER PUMP AND INSTRUCTS PATIENT TO CONNECT PATIENT MODEM CABLE TO PATIENT PUMP.	
PUMP TELLS MODEM TO TURN ON SPEAKER	PATIENT CONNECTS PATIENT MODEM CABLE TO PATIENT PUMP
CAREGIVER ASKS PATIENT TO VERIFY THAT PATIENT PUMP HAS RESPONDED WITH "PRESS ENTER TO START SLAVE COMMUNICATIONS" MESSAGE ON THE DISPLAY. CAREGIVER INSTRUCTS PATIENT TO PRESS ENTER KEY, THEN, WITHOUT HANGING UP THE PHONE, TO LISTEN FOR FURTHER INSTRUCTIONS, COMING FROM THE MODEM SPEAKER.	
	PATIENT PRESSES ENTER KEY
	PUMP TELLS MODEM TO START SLAVE COMMUNICATIONS. PUMP STARTS TWO MINUTE TIME OUT WHILE WAITING FOR CARRIER DETECT FROM MODEM.
	MODEM GOES OFF-HOOK
	MODEM DISCONNECTS PHONE
	MODEM TURNS ON SPEAKER
	MODEM SENDS SHORT BEEP TO CAREGIVER PUMP THEN LISTENS FOR CARRIER

FIG6A

7/10

	300
302	
CAREGIVER HEARS SHORT MODEM BEEP EITHER FROM PHONE HANDPIECE OR MODEM SPEAKER AND KNOWS THAT THE PATIENT PUMP IS READY	PATIENT SETS PHONE DOWN WITHOUT HANGING UP
CAREGIVER PRESSES ENTER KEY	
PUMP TELLS MODEM TO START MASTER COMMUNICATIONS, THEN PUMP WAITS FOR INCOMING DATA. PUMP STARTS TWO MINUTE TIME OUT WHILE WAITING FOR RESPONSE FROM PATIENT PUMP	
MODEM GOES OFF-HOOK	
MODEM DISCONNECTS PHONE	
MODEM SENDS CARRIER	
CAREGIVER SETS PHONE DOWN WITHOUT HANGING UP	MODEM RECEIVES CARRIER, THEN SENDS "CARRIER RECEIVED" SIGNAL TO PATIENT PUMP
	PUMP TELLS MODEM TO SHUT OFF SPEAKER
	MODEM SHUTS OFF SPEAKER
	PUMP SENDS "I'M HERE" SIGNAL TO CAREGIVER PUMP
PUMP ACKNOWLEDGES "I'M HERE" SIGNAL AND SENDS "OK TO BEGIN" SIGNAL TO PATIENT PUMP	
PUMP TELLS MODEM TO SHUT OFF SPEAKER	PATIENT PUMP RECEIVES "OKAY TO BEGIN" SIGNAL AND SENDS CURRENT DISPLAY SIGNAL TO CAREGIVER PUMP
MODEM SHUTS OFF SPEAKER	
PUMP SENDS KEY INPUT SIGNALS TO PATIENT PUMP	PUMP SENDS DISPLAY SIGNALS TO CAREGIVER PUMP IN RESPONSE TO KEY INPUT SIGNALS

FIG. 6B

400

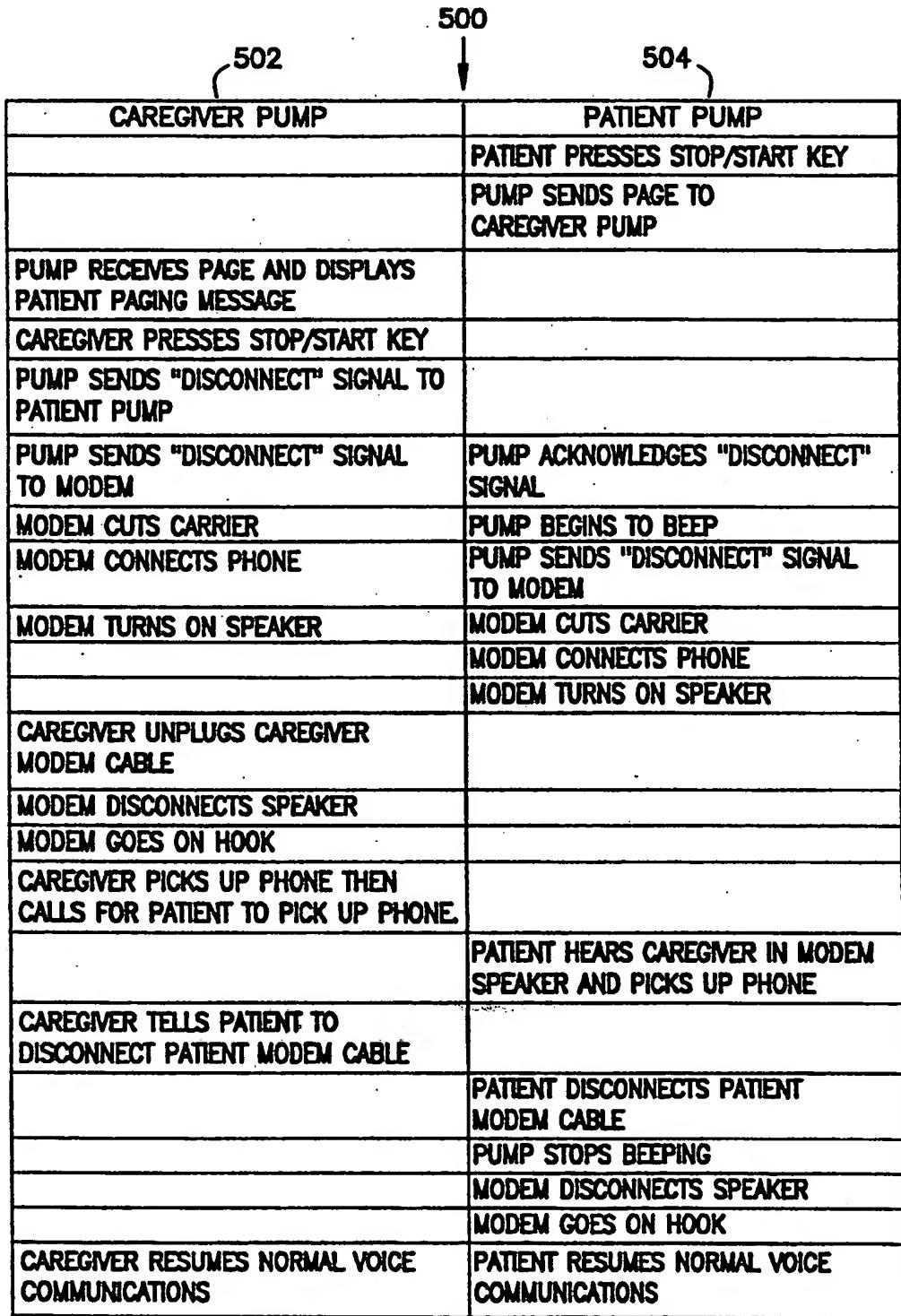
402

404

CAREGIVER PUMP	PATIENT PUMP
CAREGIVER PRESSES STOP/START KEY	
PUMP SENDS "DISCONNECT" SIGNAL TO PATIENT PUMP	
PUMP SENDS "DISCONNECT" SIGNAL TO MODEM	PUMP ACKNOWLEDGES "DISCONNECT" SIGNAL
MODEM CUTS CARRIER	PUMP BEGINS TO BEEP
MODEM CONNECTS PHONE	PUMP SENDS "DISCONNECT" SIGNAL TO MODEM
MODEM TURNS ON SPEAKER	MODEM CUTS CARRIER
	MODEM CONNECTS PHONE
	MODEM TURNS ON SPEAKER
CAREGIVER UNPLUGS CAREGIVER MODEM CABLE	
MODEM DISCONNECTS SPEAKER	
MODEM GOES ON HOOK	
CAREGIVER PICKS UP PHONE THEN CALLS FOR PATIENT TO PICK UP PHONE	
	PATIENT HEARS CAREGIVER IN MODEM SPEAKER AND PICKS UP PHONE
CAREGIVER TELLS PATIENT TO DISCONNECT PATIENT MODEM CABLE	
	PATIENT DISCONNECTS PATIENT MODEM CABLE
	PUMP STOPS BEEPING
	MODEM DISCONNECTS SPEAKER
	MODEM GOES ON HOOK
CAREGIVER RESUMES NORMAL VOICE COMMUNICATIONS	PATIENT RESUMES NORMAL VOICE COMMUNICATIONS

FIG. 7

9 / 10



**FIG. 8**

FIG. 9

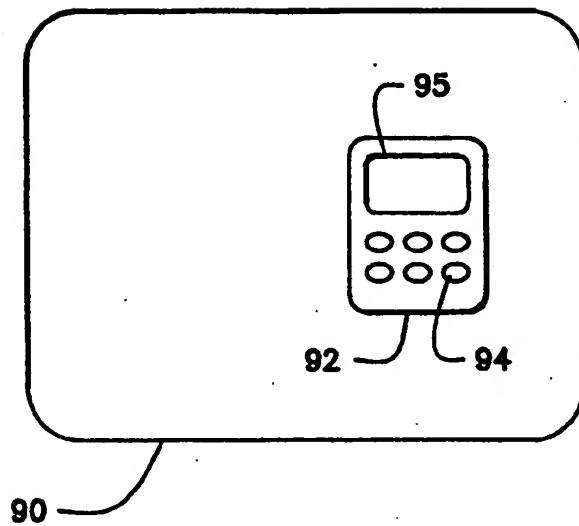
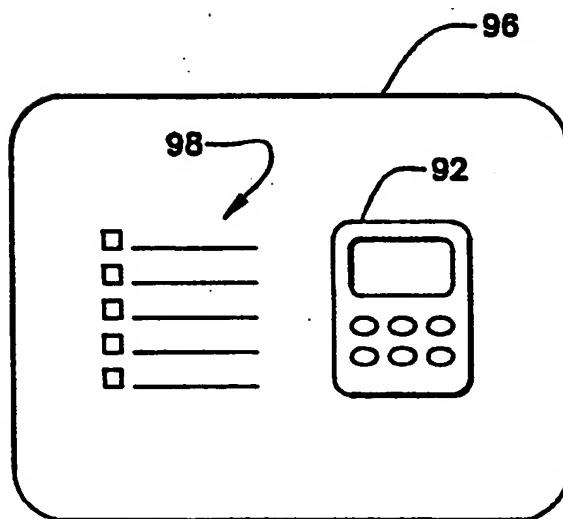


FIG. 10



## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 93/08098A. CLASSIFICATION OF SUBJECT MATTER  
IPC 5 A61M5/172 G06F15/42

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 5 A61M G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP,A,0 233 115 (BERTIN & CIE) 19 August 1987	14
A	see claims 1,16,18	1-13, 15-19
Y	US,A,4 649 499 (SUTTON ET AL.) 10 March 1987 see claim 1	14
A	US,A,4 624 661 (ARIMOND) 25 November 1986 see claim 1	1-19
A	EP,A,0 319 272 (PACESETTER INFUSION LTD.) 7 June 1989 see claims	1,14,15
		-/-

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

## \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1 Date of the actual completion of the international search

30 December 1993

Date of mailing of the international search report

11.01.94

## Name and mailing address of the ISA

European Patent Office, P.O. Box 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+ 31-70) 340-2040, Telex 31 651 epo nl.  
Fax: (+ 31-70) 340-3016

## Authorized officer

Villeneuve, J-M

## INTERNATIONAL SEARCH REPORT

Internal Application No  
PCT/US 93/08098

C(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Description of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	FR,A,2 675 288 (CWS ELECTRONICS) 16 October 1992 see claim 1 ---	1,14,15
A,P	US,A,5 153 827 (COUTRÉ ET AL.) 6 October 1992 see column 14, line 60 - column 16, line 20 -----	1,14,15

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 93/08098

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A-0233115	19-08-87	FR-A-	2593951	07-08-87
		US-A-	4778449	18-10-88
US-A-4649499	10-03-87	GB-A,B	2156114	02-10-85
		JP-A-	60215231	28-10-85
US-A-4624661	25-11-86	NONE		
EP-A-0319272	07-06-89	JP-A-	1308568	13-12-89
FR-A-2675288	16-10-92	NONE		
US-A-5153827	06-10-92	CA-A-	2008715	30-07-90